MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM

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GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES FOR THE USE OF SEALED SOURCES IN PORTABLE AND SEMI-PORTABLE GAUGING DEVICES

Massachusetts Department of Public Health
Radiation Control Program
174 Portland Street, 5th Fl.
Boston, MA 02114

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I INTRODUCTION

A. Purpose of Instructions

This guide describe the type of information needed to evaluate an application for a specific license for receipt, possession, use, and transfer of radioactive material contained in portable and semiportable gauging devices, such as moisture-density gauges and X-ray fluorescence analyzers. This type of license is provided for under the Massachusetts Regulations for the Control of Radiation (105 CMR 120.000 et. seq.), hereafter called the Regulations. The licensee should carefully review these Regulations and should use them in conjunction with this guide.

This document is intended solely for guidance in the preparation of the license application and should not be considered a substitute for the applicant's careful safety evaluation of the proposed use of radioactive material. The applicant must ensure that the application correctly and adequately describes his/her radiation safety measures and procedures.

B. Applicable Regulations

The requirements for Specific Licenses are codified in the Regulations under the general heading of Specific Licenses (105 CMR 120.124 through 120.135). Other areas of the Regulations that are applicable to this type of license are:

- 105 CMR 120.001, "General Provisions";
- 105 CMR 120.200, "Standards for Protection Against Radiation" which describes radiation safety limits;
- 105 CMR 120.750, "Notices, Instructions, and Reports to Workers: Inspections" which describes training information;
- 105 CMR 120.770, "Packaging and Transportation of Radioactive Material" which describes limits for transporting materials; and
- 105 CMR 120.890, "Low-level radioactive waste minimization regulations general provisions".

C. As Low as is Reasonably Achievable (ALARA)

Persons engaged in activities authorized by radioactive material licenses issued by the Agency should, in addition to complying with the requirements set forth in the regulations, make every reasonable effort to maintain radiation exposures as low as is

reasonably achievable (ALARA). License applicants should give consideration to the ALARA philosophy in the development of plans for work with radioactive material.

II. FILING AN APPLICATION

An application for a specific license can be made by completing Agency form MRCP 120.100-4 (Attachment A) as follows:

1. Complete Items 1 through 4 and 13 on the form itself. For Items 5 through 12, submit the required information on supplementary pages.

2. Identify and key each separate sheet or document submitted with the application to the item's number of the application to which it refers.

3. All typed pages, sketches, and, if possible, drawings should be on 8-1/2 x 11 inch paper to facilitate handling and review. If larger drawings are necessary, fold them to 8-1/2 x 11 inches.

4. Complete all items in the application in sufficient detail so that the Agency can determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and minimize danger to life and property.

5. Please note that license applications are available for review by the public. Do not submit proprietary information unless necessary. If proprietary information is submitted without proper documentation that confidentiality must be maintained, there may be disclosure of the proprietary information to the public or time-consuming delays in processing your application.

6. Do not submit personal information about your individual employees unless it is pertinent to the application. Training and experience of individuals should be submitted to demonstrate their ability to manage radiation safety programs or to work safely with radioactive materials. A person specifically listed as an authorized user on an existing radioactive material license may submit a copy of that license (or reference an Agency Radioactive Material License Number) as evidence of training and experience. Submit home addresses and home telephone numbers only if they are part of an emergency response plan. Do not submit birthdates, Social Security numbers, and radiation dose information unless specifically requested by the Agency.

7. The application should be completed in triplicate. The original and one copy of the application, along with duplicate copies of supporting documents, should be sent to:

Massachusetts Department of Public Health
Radiation Control Program, 5th Floor
174 Portland Street
Boston, MA 02114

8. Retain one copy of the entire application for yourself. The license is issued based on the statements and representations in your application and any supplements to it, as well as the requirements in the regulations.

III. INFORMATION TO BE SUBMITTED

Since the space on the application form is not sufficient to contain all the required information, additional sheets should be appended.

Each separate sheet or document submitted with the application should be identified by a heading indicating the appropriate application item number and its purpose.

Item 1 - LICENSE INFORMATION

For a new license, check subitem A. For an amendment to an existing license, check subitem B. For a renewal of an existing license, check subitem C.

Item 2 - APPLICANT'S NAME AND MAILING ADDRESS

If you are filing as an individual, you should be designated as the applicant only if you are acting in a private capacity and the use of the radioactive material is not connected with your employment with a corporation or other legal entity. Otherwise, the applicant should be the corporation or other legal entity applying for the license.

The address specified here should be the applicant's mailing address for correspondence. This may or may not be the same as the address at which the material will be used as specified in Item 3.

Item 3 - LOCATIONS OF USE

Specify each location of use. List the street address, city, and state or other descriptive address (such as 5 miles from the intersection of Route 32 on Highway 10, Anytown, State) to allow us to locate your facilities. A post office box address is not acceptable.

If you will conduct operations at temporary job sites, you may specify "temporary job sites in Massachusetts". You must describe the intended use and the facilities and equipment at each location. Use Items 5 through 11 of the application to describe uses at multiple locations.

Item 4 - PERSON TO BE CONTACTED ABOUT APPLICATION

Provide the name and telephone number of the individual who is most familiar with your proposed radioactive materials program and can answer questions about the application. This individual, usually the RSO or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this individual is not your full-time paid employee, specify your relationship with this individual. Notify the Agency if the individual assigned to this function changes. Notification of a contact change is for information only and would not be considered an application for a license amendment.

Item 5 RADIOACTIVE MATERIAL

Submit a detailed description of the radioactive material for which a license is desired. This description should include all the items listed in the following example:

Element and Mass Number:.....	Cs-137
Chemical and Physical Form:.....	Sealed Source
Source Manufacturer(s) and Model:.....	Troxler, A-102112
Maximum Activity per Source:.....	9 mCi
Device Manufacturer and Model:.....	Troxler 3400 Series
Number of Sources Requested:.....	5

Item 6 PURPOSE

The manufacturer's name and model number of each gauge or device utilizing the sources listed in Item 5 must be specified and keyed to the listed sources. In addition, the purpose for which the gauges or devices will be used must be stated, for example, "Moisture-density gauges to be used for measuring moisture and surface density of construction materials."

The information specified in Items 5 and 6 is available from the manufacturer of the device.

Item 7 - INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAMS--THEIR TRAINING AND EXPERIENCE

If multiple users will be listed, a radiation safety officer must be designated to implement the radiation safety program. State the name of the radiation safety officer. This person is designated by, and responsible to, the organization's management for the coordination of the organization's radiation safety program and for ensuring compliance with the applicable parts of the regulations.

The individual responsible for the radiation safety program, at a minimum, should have completed the device manufacturer's training program or should have received equivalent training. If the responsible individual has completed or will complete the device manufacturer's program, enclose a copy of the completion certificate or state in the application the title of the course, when and where the course will be completed, and the name of the course instructor.

If the responsible individual has received training other than that provided by the device manufacturer or an equivalent, Agency approved course, state when and where the training was received, the topics covered in the training, and the name and qualifications of the training instructor. The instructor should have completed an approved training course and should have at least one year of experience in the use of portable gauging devices. At a minimum, the topics covered in the training should include radiation safety principles and practices for using the device, regulatory requirements pertaining to the use, storage and transportation of the device, and instructions and practice in using the device.

Specify the duties and responsibilities of the radiation safety officer. These duties and responsibilities should include, at a minimum, the duties and responsibilities listed in Appendix A.

Item 8 - RADIOLOGICAL QUALIFICATIONS AND TRAINING

Personnel who will independently use devices containing radioactive material do not need to be designated by name. However, if the applicant does not specifically identify all individuals that should be authorized to use radioactive material independently, and include training and experience for each individual identified, then the applicant must provided a commitment that all authorized users will complete either:

A. An approved device manufacturer's training program, or

B. A training program equivalent to the device manufacturer's training program. If this option is choosen, then either specify the equivalent training program, or for in-house training programs, submit the information specified in Note below.

Regardless of which option is chosen, the applicant should provide a commitment that training records will be maintained (e.g., copies of training course certificates issued to each authorized user) for all personnel authorized to use the device independently.

If any individual was previously approved to use portable x-ray fluorescence analyzers or other portable device containing a sealed source on another specific license, then simply submit a copy of that license (or reference a Massachusetts Radioactive Material License Number). License renewals that do not request the addition of new users may simply reference the current license for evidence of user training and experience without submitting additional training documentation.

[NOTE: The applicant may request authorization to provide in-house training to authorize new radioactive material users without sending those individuals to the manufacturer's (or equivalent) training course. In order for Agency staff to evaluate proposals for in-house training programs, submit the following information:

A. Specify the individual who will provide the in-house training and submit that individual's training and experience relative to radioactive material use. The instructor should have completed an approved training course and should have at least one year of experience in the use of portable gauging devices.

B. Describe the form of training (e.g., formal course work, lectures, supervised, on-the-job training, etc.) to be provided, specify the duration of this training,

and describe the topics that will be covered. The subject matter covered should include, at a minimum, radiation safety principles and practices for using the device, regulatory requirements pertaining to the use, storage and transportation of the device, and instructions and hands-on practice in using the device under the direct supervision of an authorized user.

C. Submit a sample copy of the exam that will be given on the subjects covered in Item B. Of this NOTE, including a copy of the answers. In addition, specify the criteria which will be used to determine a passing score (e.g., 80% correct on the written exam and demonstrated competency on the use of the device while under the direct supervision of an authorized user).

D. Verify that records of user training and approval will be maintained for Agency inspection and that the records will contain, at a minimum, the following information:

1. The instructor's name and signature;

2. The trainee's name;

3. The date(s) on which training was given;

4. The topics covered during training and the results of all examinations administered;

5. A pass or fail indication of the trainee's demonstrated competency in using the device while under the direct supervision of an authorized user; and

6. A statement which clearly indicates whether the trainee is approved by the instructor to use the device independently under the authorizations of the license.**]**

Item 9 FACILITIES AND EQUIPMENT:

Devices must be stored in such a manner as to prevent unauthorized removal or unauthorized use as required by 105 CMR 120.235. Submit an annotated sketch or sketches of the storage area(s), closet(s), etc., showing the relationship of the storage area to other adjoining areas. Also provide a description of the

security measures taken to limit access to the storage areas to authorized personnel only (e.g., areas locked when not in use by authorized users and keys possessed by authorized users only).

In addition, for each permanent storage or use location, submit a letter from the owner of that property which verifies that the owner understands radioactive material will be stored and/or used on that property.

Item 10 RADIATION SAFETY PROGRAM

Procedures should be established to ensure compliance with the provisions of 105 CMR 120.200, "Standards for Protection Against Radiation," and 105 CMR 120.750, "Notices, Instructions and Reports to Workers, Inspections."

Specify the individuals authorized to order radioactive material and ensure that requested radioactive material does not exceed the limits authorized by the license.

Submit procedures for the receipt of radioactive material. In the procedures address the receipt of radioactive material during and after normal working hours and the individuals authorized to receive the material. If radioactive material will not be received after normal working hours, so indicate.

Submit a copy of the applicant's written radiation safety procedures. The procedures should be in the form of written instructions to users and should cover the following items:

A. Safety measures to be used when transporting the device(s) in a vehicle (e.g., fully secured within the vehicle and away from the passenger compartment). Transportation activities must be carried out in accordance with 105 CMR 120.770 and the requirements of the U.S. Department of Transportation regulations (e.g., approved transport container, proper labeling and marking, shipping papers, containers braced and blocked, etc.).

B. Procedures or methods for preventing unauthorized access, use or removal of the device at temporary job sites. Instructions should state that individual users are never to leave a device unattended unless the device is secured from unauthorized access (e.g., locked within a transport vehicle to which only authorized users have a key).

C. Procedures or methods for preventing unauthorized access, use or removal of devices from the designated place(s) of storage at permanent locations.

D. Procedures to be followed for maintenance of records regarding receipt, use and transfer of radioactive material. Records of use should be adequate to identify the location of the devices at all times (see Appendix E for a sample utilization log). Either verify that the applicant will use the utilization log contained in Appendix E, or submit an equivalent utilization log for Agency review.

E. Personnel monitoring procedures, including the monitoring devices to be used, their location when not in use, requirements for their use and instructions for the collection of personnel monitoring devices at appropriate intervals. Either provide the information requested here or state that you will maitain, for Agency inspection, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of 10% of the allowable limits in 105 CMR 120.200.

F. Specific instructions to users informing them that any maintenance on the devices involving dismantling, removal of source holder(s), repair, etc., must be performed only by the manufacturer or other persons specifically authorized to perform such repairs by the Agency, another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission.

[NOTE: If the applicant desires authorization to perform maintenance and repair on devices involving access to the source holders, and/or dismantling of the shielding or shutter devices, specific information on step-by-step procedures, including radiation safety precautions, must be submitted to the Agency. In addition, the names, qualifications and training of the personnel who will perform such maintenance and repair must be submitted.**]**

G. Specific instructions to the users informing them that:

1. The source holder shall be locked in the "off" or closed position when the device is not in use;

2. Sealed sources shall not be opened or removed from their source holders by the licensee; and

3. Current copies of the following documents shall be maintained at temporary job sites for Agency inspection:

   (a) The manufacturer's instruction manual with appropriate emergency procedures; and

   (b) A copy of the results of the latest test for leakage and/or contamination performed on the

sealed source.

10.1 Operating and Emergency Procedures

The applicant should submit a copy of his written radiation safety and emergency procedures provided to his users of the gauges or devices, such as:

A. Safety measures to be used in transporting the devices in the applicants, vehicle (for example, fully secured within the transportation vehicle and away from the passenger compartment). Transportation activities must be carried out in accordance with the requirements of 105 CMR 120.770, "Transportation of Radioactive Material."

B. Means of preventing unauthorized access, use or removal of the gauges from temporary job sites.

C. Means of preventing unauthorized use or removal of gauges from the designated place(s) of storage.

D. Emergency procedures to be followed in case of accidents involving damage or loss of the gauges or devices, including names and telephone numbers of the individual(s) within the applicant's organization who should be notified and who would, in turn, notify the local police, and the Agency at (617) 727-6214. The Agency's 24-hour number should be included in this section (617/727-9710).

E. Specific instructions to the users informing them that any maintenance on the gauges involving dismantling, removal of source holder(s) etc., must not be performed by the user and must only be performed by the manufacturer of the device, unless the applicant has specifically requested authority for performing maintenance in the application.

If the applicant wishes to be authorized to perform maintenance and repair on gauges and devices involving access to the source holders, and/or dismantling of the shielding or shutter devices, specific information on the step-by-step procedures to be followed including radiation safety precautions must be supplied. In addition, the names of the personnel and the specific pertinent training of the personnel who will be performing such maintenance and repair must be given.

Radiation detection instruments are not normally required for most licensees if the devices are used for their intended purpose, transported in U.S. Department of Transportation

approved containers, and no maintenance procedures involving access to the sources and source holders are performed. However, if maintenance involving access to the sources and source holders is performed, at least one low range beta-gamma (0-50 mR/hr or 0-200 mR/hr) survey instrument must be available at each maintenance area for monitoring during and upon completion of the maintenance procedures.

If maintenance procedures involving access to the source or source holder is requested, then submit the following information for each radiation detection instrument:

A. Instrument Manufacturer;
B. Instrument Model Number;
C. Detector Manufacturer;
D. Detector Model Number;
E. Detection Range; and
F. Quantity On-Hand.

10.2 Calibration of Radiation Detection Instrumentation

If radiation detection instruments are required (per Item 10.1), then they must be calibrated at intervals not to exceed one year. Indicate whether instrument calibrations will be performed by the applicant or a calibration service licensed by the Agency, another Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission. If the applicant chooses to calibrate their own radiation detection instruments, then submit the information requested in Appendix B, and either verify that the procedures for instrument calibration contained in Appendix B will be followed, or submit equivalent procedures for Agency review.

Regardless of which option is chosen, the applicant should verify that quarterly operational checks, for radiation detection instruments, will be performed in accordance with the procedure contained in Appendix B and that records of instrument calibrations and quarterly operational checks will be maintained for Agency inspection.

10.3 Leak Testing of Sealed Sources

Leak testing of sealed sources may be performed only by an organization or individual specifically licensed by the Agency, an Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission to perform such services. In establishing a program for leak testing, three alternatives are available from which to choose:

1. The services of a licensed consultant or commercial organization may be used to obtain leak test samples, evaluate the samples, and report the results back to the applicant. If the firm is specifically licensed by this Agency, please indicate its Massachusetts Radioactive Material License Number. If the firm is specifically licensed by an Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission, then submit a copy of the license authorizing the firm to provide such leak test services.

2. A commercially available leak test kit may be used to obtain leak test samples for subsequent analysis by a licensed service company. If this option is chosen, then submit the following information:

   A. Leak test kit manufacturer and kit model;

B. Indication that the kit will be used in accordance with the instructions provided;

C. Identification of the source or device to be tested with the kit; and

D. Identification of the firm performing the analysis of the leak test samples. If the firm is specifically licensed by this Agency, include its Massachusetts Radioactive Material License Number. If the firm is specifically licensed by an Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission, then submit a copy of the license authorizing the firm to provide such leak test services.

3. The applicant may request authorization to perform leak tests, including sampling and analysis. If this option is chosen, then submit the information outlined in Appendix D for Agency evaluation.

Regardless of which option is chosen, specify the frequency at which leak tests will be performed for sealed sources used in gas chromatographs, x-ray fluorescence analyzers or other non-portable device. Most sources used in these types of devices are evaluated and approved for a six month leak test frequency. Note that detector cells containing tritium (H-3) are not required to be leak tested.

Item 11 WASTE MANAGEMENT:

11.1 Waste Disposal:

Because of the nature of the licensed material contained in devices, your only option for disposal is to transfer the material to an authorized recipient. You should state that disposal will be by transfer of the radioactive material to a licensee specifically authorized to possess it.

Authorized recipients are the original supplier of the device, a commercial firm licensed by DPH, NRC, or another Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material. No one else is authorized to dispose of your licensed material.

11.2 Waste Minimization:

105 CMR 120.890 requires that all radioactive material users, as

well as all generators, of radioactive waste must prepare a statement indicating the measures they have taken to minimize any waste that may result from their operations. Those applicant whose operation result in 100 cubic feet or more of waste per annum, and such waste requires disposal, must develop and institute waste minimization programs predicted on detailed plans. Provide an approriate document that applies to your operation.

[**NOTE]:** It would be adequate if you:
Describe the specific method(s) to be used to dispose of the device(s) containing radioactive material when the device(s) are no longer usable or wanted (e.g., return to the manufacturer).]

Item 12 - ORGANIZATIONAL STRUCTURE

Provide an organizational chart both for the institution, showing Administration, Radiation Safety Committee and Radiation Safety Officer, and for the corporate structure and ownership. Identify the state of incorporation, and provide the names of principal stockholders, if applicable. List parent companies, names, addresses, and titles of principals. List percentages of partners, shares, state of incorporation, and other organizational details that may be important during financial or legal circumstances.

Item 13 - CERTIFICATION

Identify the title of the office held by the individual who signed the application.

IV AMENDMENT OF A LICENSES

A licensee must receive a license amendment before changing the scope of the program, changing the Radiation Safety Officer or adding to the staff of authorized users. An application for an amendment must be filed either on agency Form MRCP 120.100-4 or as a letter and must be signed.

V RENEWAL OF A LICENSES

An application for the renewal of a license should be filed at least 60 days before the expiration date. This will ensure that the license does not expire before final action on the application has been taken by the Agency as provided for in 105 CMR section 120.133. The application for renewal must be filed on Agency form MRCP 120.100-4. The application for renewal may reference attachments that were previously submitted. For example, "See ATT 10.7 dated November 14, 1992."

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LIST OF APPENDICES

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APPENDIX A

RADIATION SAFETY OFFICER

Among the specific duties and responsibilities of the radiation safety officer are the following:

A. Assure that radioactive material possessed under the license conforms to the material authorized by the license.

B. Assure that only individuals authorized by the license use the radioactive material.

C. Assure that radioactive material is properly secured against unauthorized removal at all times when not in use.

D. Serve as a point of contact with the Agency and give assistance in case of emergency (e.g., damage, fire, theft, etc.).

E. Assure that the proper authorities (i.e., Massachusetts Radiation Control Program, local police, U.S. Department of Transportation, etc.) are notified promptly in case of accident, damage, theft or loss.

F. Assure that the terms and conditions of the license (such as periodic leak tests) are met and that the required records (such as leak test, accountability, etc.) are maintained and periodically reviewed for compliance with Agency regulations and license conditions.

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APPENDIX B

SAMPLE MINIMUM DETECTABLE ACTIVITY CALCULATIONS

Several references contain discussions of counting statistics for radiation measurements. For purposes of this guide, the discussion contained in NCRP Report No. 58 appears to be the simplest to use. The formula we recommend is the one for determining a measurement at the 95% confidence level. The formula for this level is:

$$LLD = \frac{2.71 + 4.65\sqrt{B}}{EFF}$$

where:

LLD = Lower Limit of Detection (dpm, divide by 2.2 E+6 for µCi)

B = Background counting rate (counts/time), and

EFF = Counting efficiency.

The sample counting time and background counting time must be equal. The counting efficiency must be determined by using a standard source of known activity that emits photons of approximately the same energy as the contaminant to be detected. The counting rate for the standard is divided by the standard activity to determine the counting efficiency. When dividing, the two values must be in compatible units. For example, a standard activity in FCi must be converted to dpm by multiplying by a factor of 2.2E+6.

For a copy of the full discussion of the theory and limitations of this test, refer to pages 307-311 in NCRP Report No. 58, A Handbook of Radioactivity Measurement Procedures, issued February 1, 1985 by the National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Bethesda, MD 20814.

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APPENDIX C

RECOMMENDED METHOD FOR CALIBRATING
RADIATION DETECTION INSTRUMENTS

1. Application For a Licensee to Perform Radiation Detection Instrument Calibrations

When radioactive material is used to calibrate radiation detection instruments, the person or organization performing the calibration must be specifically authorized by the Agency, the U. S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

An application for a licensee to perform radiation detection instrument calibrations should contain the following information:

a. The manufacturer's name and model of the source(s) to be used.

b. The radionuclide and activity of the radioactive material contained in the source(s).

c. The accuracy of the source(s) activity; documentation that the determination of each source activity is traceable to the National Institute of Standards and Technology - NIST (previously National Bureau of Standards - NBS).

d. A description of the facilities to be used.

e. The name and applicable experience of each individual who will perform the calibrations.

f. Calculations related to the calibration procedures.

g. The step-by-step calibration procedures, including associated radiation safety procedures.

h. Copies of records that will be maintained (see Item 4).

i. Verification that the requirements outlined in this appendix will be followed.

2. Recommended Methods For Calibration of Radiation Detection Instruments

The calibration of radiation detection instruments shall be

performed in accordance with the following:

a. The radionuclide sources used for calibration shall approximate point sources.

b. The source activities shall be traceable* within ±5% accuracy to the NIST (previously NBS) calibrations.**

c. The frequency of calibration shall be at intervals not to exceed one year and after servicing/repair.

d. Each scale of the radiation detection instrument shall be calibrated at least at two points such that: (a) one point is in each half of the scale; and (b) the two points are separated by 50-60% of full scale. Logarithmic and digital readout radiation detection instruments with only a single readout scale shall be calibrated, at a minimum, at one point near the midpoint of each decade.

e. The exposure rate measured by the radiation detection instrument should not deviate more than ±10% from the calculated or known value for each point checked. (Read appropriate section of the radiation detection instrument manual to determine how to make necessary adjustments to bring the radiation detection instrument into calibration.) Readings within ±20% will be considered acceptable if a calibration chart or graph is prepared and attached to the radiation detection instrument. If the radiation detection instrument cannot be adjusted so that each reading falls within the ±20% range, it shall be taken out of service and sent to the manufacturer or to a qualified radiation detection instrument laboratory for repair.

f. If an electronic device is used to calibrate instruments, the instrument must still be checked for response to a known source of radiation.

NOTE: Sources of cobalt-60, cesium-137, or radium-226 are appropriate for use in calibrations. The radioactivity of the calibration standard should be sufficient to calibrate the radiation detection instruments on all ranges, or at least up to 1 Roentgen per hour on the higher range radiation measurement instruments. If there are higher ranges, they should be checked for operation and approximately correct response to radiation.

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* For purposes of this document, the amount of radioactivity in a source is said to be traceable to a national standard when its radioactivity was determined by comparison with a source of the same radionuclide (or a proper simulated source, isotopically) the activity of which is certified by the NIST.

** In lieu of using a traceable radioactive source, a transfer instrument traceable to the NIST, within ±5%, may be used as an alternative standard. For purposes of this document, a transfer instrument shall meet the definition as contained in the American National Standard Institute publication, ANSI N323-1978, "Radiation Protection Instrumentation Test and Calibration."

3. Use of a Reference Check Source for Operational Checks

A reference check source of a long half-life (e.g., greater than five years) shall be used to obtain a radiation detection instrument response by the licensee. The reading shall be taken with the check source placed in a specific geometry relative to the detector, and:

a. Shall be taken before use on each day the instrument is used;

b. Shall be taken after calibration by the licensee or after return to the licensee of a radiation detection instrument sent for calibration by a specifically licensed firm authorized to perform radiation detection instrument calibrations as a customer service;

c. Shall be taken after maintenance and/or each battery change; and

d. Shall be taken at least quarterly.

If any operational check reading using the reference check source, with the same geometry, is not within ±20% of the reading measured immediately after calibration (or upon receipt from a calibration firm), the radiation detection instrument shall be removed from service and recalibrated.

4. Records

Records for Items 2, 3.b, 3.c, and 3.d of this procedure shall be maintained.

a. Records for Item 2 shall include, at a minimum:

1) Radionuclide used;
2) Activity and assay date of source;
3) Present activity;
4) Calculated and measured radiation values, including the percentage of difference;
5) Respective distance from source for each calculated and measured radiation value;
6) Necessary scale correction factors (required if calculated and measured radiation values do not agree within ±10%);
7) Make, model and serial number of radiation detection instrument being calibrated;
8) Name of individual performing the calibration; and
9) Date radiation detection instrument calibration was performed.

b. Records for Items 3.b, 3.c, and 3.d of this procedure shall include, at a minimum:

1) Radionuclide used;
2) Activity and assay date of the radionuclide used;
3) Reading of check source at time of calibration;
4) Geometry of check source relative to detector (position);
5) Date of calibration;
6) Make, model and serial number of the radiation detection instrument;
7) Date reference check was performed; and
8) Name of individual who performed the reference check.

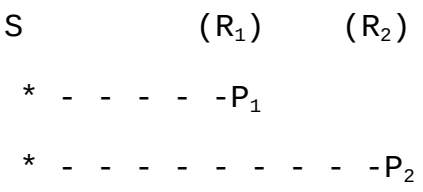
5. Use of Inverse Square Law and Radioactive Decay Law

a. A calibrated source will have a calibration certificate giving its output at a given distance measured on a specific date by the manufacturer or National Institute of Standards and Technology (NIST).

1) The Inverse Square Law may be used with any point source to calculate the exposure rate at other distances.

2) The Radioactive Decay Law may be used to calculate the output at other times after the specified date.

b. INVERSE SQUARE LAW:



Exposure rate at P_2:

$$R_2 = \frac{(P_1)^2 \times (R_1)}{(P_2)^2}$$

where:

S is the point source

R_1 and R_2 are the exposure rates at P_1 and P_2 in the same units (mR/hr or R/hr).

P_1 and P_2 are the distances from the point source in the same units
(centimeters, meters, feet, etc.)

c. RADIOACTIVE DECAY LAW:

$$R_t = R_o \, e^{-(0.693 \, t \, / T_{1/2})}$$

where:

R_o and R_t are in the same units (mR/hr or R/hr)

R_o is exposure rate on specified calibration date (time zero)

R_t is exposure rate "t" units of time later

$T_{1/2}$ and t are in the same units (years, months, days, etc.)

$T_{1/2}$ is half-life of the radionuclide

t is the time elapsed between the source calibration (assay) date and the radiation detection instrument calibration date (present time)

d. Example: Source output is given by calibration certificate as 100 mR/hr at 1 foot on March 10, 1985. Radionuclide half-life is 5.27 years.

Question: What is the output at 3 feet on March 10, 1987 (2.0 years later)?

1) Output at 1 foot, 2.0 years after calibration date:

$$R_{(1 \text{ ft})} = 100 \text{ mR/hr } [\exp^{-((0.693 \times 2.0)/5.27)}]$$

$$= 100 \text{ mR/hr } (0.77)$$

$$= 77 \text{ mR/hr at 1 foot on March 10, 1987}$$

2) Output at 3 feet, 2.0 years after calibration date:

$$(1 \text{ foot})^2$$

$$R_{(3\ \text{feet})} = \frac{}{(3\ \text{feet})^2}\ (77\ \text{mR/hr})$$

$$= 1/9\ (77\ \text{mR/hr})$$

$$= 8.6\ \text{mR/hr at 3 feet on March 10, 1987}$$

APPENDIX D

LEAK TESTING OF SEALED SOURCES

Distributors of sealed sources usually supply a certificate with each source giving the results and the date of the last leak test performed on such sources. If such a certificate is not received with a source, the source is not to be used until a leak test is performed and the results of the test are received showing that the source is not leaking or contaminated. Thereafter, the source must be tested for leakage and contamination at intervals not to exceed six months, unless otherwise authorized. Records of the testing of each source must be maintained for Agency inspection.

Applicants who wish to perform their own leak tests, including the taking and the analysis of the test samples, must submit the following descriptive information in support of the application:

A. Describe all instrumentation which will be used for the analysis of the test samples. The descriptive information should include:

   1. The manufacturer and model of each instrument;

   2. The types and energies of detectable radiation, as it pertains to each instrument;

   3. The efficiency of each instrument, for each type of radioactive material to be tested, including the supportive calculations documenting such efficiency; and

   4. The minimum sensitivity of each instrument, for each type of radioactive material to be tested, including the supportive calculations documenting such minimum sensitivity. At a minimum, the instrument must be capable of detecting 0.005 microcuries (185 Bq) of the radioactive material being tested.

B. Identify the calibration standards to be used in the analysis of each radioactive material to be tested. The identification should include the manufacturer, model, radionuclide and activity of each standard. Such standards should be traceable to a national standard.

C. Describe the calibration procedures and the frequency of

calibration for each instrument.

D. Describe the material to be used in collecting the leak test samples.

E. Describe the radiation safety procedures to be followed during the leak test sample collection process.

F. Describe in detail the procedure for performing the analysis of the leak test samples.

G. Submit sample calculations showing the conversion of the raw counting data to units of microcuries.

H. Describe the method for handling and disposing of contaminated leak test samples.

I. Describe the training and experience of each person who will take or evaluate the leak test samples which qualifies the person for each task.

J. Include copies or facsimiles of leak test certificates that identify:

1. The name and address of the individual or firm that possesses the source which was leak tested;

2. The date the sample was collected;

3. The individual collecting the sample;

4. The person performing the analysis;

5. The date the analysis was performed;

6. The unique identification of the source tested (e.g., manufacturer, model, serial number, etc.);

7. The radionuclide and the activity of radioactive material contained in the source; and

8. The result of the test expressed in units of microcuries or becquerels. Actual test results shall be reported unless such results are less than 0.005 microcuries (185 Bq) .

K. If the applicant will be providing a leak test service to other individuals or firms, please submit:

1. Verification that a written report of the leak test results will be furnished to the customer;

2. Verification that immediate notification by telephone or telegraph will be given to the customer for each leak test result indicating leakage exceeding 0.005 microcuries; and

3. Verification that the applicant will maintain records of the results of each leak test analysis performed.

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APPENDIX E

SAMPLE UTILIZATION LOG

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MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM
UTILIZATION LOG FOR RADIOACTIVE MATERIAL

NAME OF THE USER	SOURCE OUT		SOURCE IN		NAME OF THE SOURCE	ACTIVITY (mCi)
	DATE	TIME	DATE	TIME		

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LIST OF EXHIBITS

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EXHIBIT A

APPLICATION FORM FOR RADIOACTIVE MATERIAL LICENSE
FOR THE USE OF SEALED SOURCES IN
PORTABLE GAUGING DEVICES

(Application Form MRCP 120.100-4)

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RADIOACTIVE MATERIALS LICENSE APPLICATION
MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH, RADIATION CONTROL PROGRAM

INSTRUCTIONS - Complete all items in this application for a new license or the renewal of an existing license. Use supplemental sheets where necessary. Item 13 must be completed on all applications. Mail the completed application to: The Radiation Control Program, 174 Portland Street, 5th Fl. Boston, MA 02114. Upon approval of this application, the applicant will receive a State of Massachusetts Radioactive Material License.

1. THIS IS AN APPLICATION FOR ☐ A. NEW LICENSE ☐ B. AMENDMENT TO LIC.NO._____ ☐ C. RENEWAL OF LICENSE NO._____	2. NAME AND MAILING ADDRESS OF APPLICANT(Include zip code)
3. ADDRESSES WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.	
4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION.	TELEPHONE NUMBER
SUBMIT ITEMS 5 THROUGH 12 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.	
5. RADIOACTIVE MATERIAL a. Element & mass number; b. Chemical and/or physical form; c. Maximum amount that will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFTY PROGRAM AND THEIR TRAINING AND EXPERIENCE.	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9. FACILITIES AND EQUIPMENT.	10. RADIATION SAFETY PROGRAM
11. WASTE MANAGEMENT (INCLUDE MINIMIZATION STATEMENT/PLAN).	12. CORPORATE STRUCTURE

ITEM 13 - CERTIFICATE
(This item must be completed)

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH APPLICABLE STATE REGULATIONS AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

_____ By: _____

TYPE OR PRINT NAME OF CERTIFYING OFFICIAL SIGNATURE

_____ Date: _____

TITLE OF CERTIFYING INDIVIDUAL

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You may use the table below to provide the information requested in Items 5 and 6 of the Application Form MRCP 120.100-4

MATERIAL POSSESSED

Radio-isotope	Manufacturer Model Nos. (Sealed Source)	No. of Sources	Authorized activity per source	Manufacturer Model Nos. (Gauges)	No. of devices	Authorized Use

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EXHIBIT B

CERTIFICATE - TERMINATION AND

DISPOSITION OF RADIOACTIVE MATERIAL

(FORM MRCP 120.100-3)

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Massachusetts Department of Public Health
Radiation Control Program
174 Portland Street, 5th Floor
Boston, MA 02114

The Agency is requesting disclosure of information that is necessary to accomplish the statutory purpose as outlined under M.G.L. c. 111, §§ 3, 5M, 5N, 5O, 5P. Disclosure of this information is required. Failure to provide any information will result in this form not being processed.

CERTIFICATE - TERMINATION
DISPOSITION OF RADIOACTIVE MATERIAL

LICENSEE NAME: _____ **LICENSE NUMBER:** _____

ADDRESS: _____

_____

_____

The following information is provided in accordance with 105 CMR 120.132, "Expiration and Termination of Licenses." This regulation is attached to this form. Complete the items below which are applicable to your licensed activity:

__ **1. All use of radioactive materials authorized under the above referenced license has been terminated.**

__ **2. Radioactive contamination has been removed to the level outlined in 105 CMR 120. 291 to the extent practicable.**

__ **3. All radioactive material previously procured and/or possessed under the authorization granted by the above referenced license has been disposed of as follows:**

__ **Transferred to (Name and Address):** _____

_____

_____

which is authorized to possess such material under License Number _____

issued by (Licensing Agency): _____

__ **Decayed, surveyed and disposed of as non-radioactive trash.**

__ **Licensed under License Number:** _____

issued by (Licensing Agency): _____

__ **No radioactive material has ever been procured and/or possessed by the licensee under the authorization granted by the above referenced license.**

__ **Other (Attach additional pages).**

__ **4. Attached are radiation surveys or the equivalent as specified in 105 CMR 120.132(I)(2).**

__ **5. Additional remarks. (Attach additional pages).**

THE UNDERSIGNED, ON BEHALF OF THE LICENSEE, HEREBY CERTIFIES THAT LICENSABLE QUANTITIES OF RADIOACTIVE MATERIAL UNDER THE JURISDICTION OF MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH RADIATION CONTROL PROGRAM ARE NOT POSSESSED BY THE LICENSEE. IT IS THEREFORE REQUESTED THAT THE ABOVE REFERENCED LICENSE BE TERMINATED.

DATE: _____ **SIGNATURE:** _____

TITLE: _____

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120.132: Expiration and Termination of Licenses

(A) Each specific license expires at the end of the day on the expiration date stated in the license unless the licensee has filed an application for renewal under 105 CMR 120.133 not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the Agency makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(B) Each specific license revoked by the Agency expires at the end of the day on the date of the Agency's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Agency Order.

(C) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

(1) Limit actions involving radioactive material to those related to decommissioning; and,
(2) Continue to control entry to restricted areas until they are suitable for release in accordance with Agency requirements.

(D) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in 105 CMR 120.013, each licensee shall provide notification to the Agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Agency requirements, or submit within 12 months of notification a decommissioning plan, if required by 105 CMR 120.132(F)(1) and begin decommissioning upon approval of that plan if-

(1) The license has expired pursuant to 105 CMR 120.132(A) or (B); or,
(2) The licensee has decided to permanently cease principal activities, as defined in 105 CMR 120.132, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements: or,
(3) No principal activities under the license have been conducted for a period of 24 months; or,
(4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements.

(E) The Agency may grant a request to extend the time periods established in 105 CMR 120.132(D) if the Agency determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to 105 CMR 120.132(D). The schedule for decommissioning set forth in 105 CMR 120.132(D) may not commence until the Agency has made a determination on the request.

(F) (1) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor have not been previously approved by the Agency and these procedures could increase potential health and Safety impacts to workers or to the public, such as in any of the following cases:

(a) procedures would involve techniques not applied routinely during cleanup or maintenance operations;
(b) workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;
(c) procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or,
(d) procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The Agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to 105 CMR 120.132(D) if the Agency determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.
(3) Procedures such as those listed in 105 CMR 120.132(F)(1) with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

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(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:
(a) a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;
(b) a description of planned decommissioning activities;
(c) a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;
(d) a description of the planned final radiation survey; and,
(e) an updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.
(f) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in 105 CMR 120.132(H).

(5) The proposed decommissioning plan will be approved by the Agency if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(G) (1) Except as provided in 105 CMR 120.132(B), licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(2) Except as provided in 105 CMR 120.132(H), when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(H) The Agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Agency determines that the alternative is warranted by consideration of the following:

(1) whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(2) whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period:

(3) whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and,

(5) other site-specific factors which the Agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration,actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(I) As the final step in decommissioning, the licensee shall-

(1) Certify the disposition of all licensed material including accumulated wastes, by submitting a completed Agency Form MRCP 120.100-3 or equivalent information; and,

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey unless the licensee demonstrates that the premises are suitable for release in some other manner. The licensee shall, as appropriate-

(a) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters -removable and fixed - for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and,
(b) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(J) Specific licenses, including expired licenses, will be terminated written notice to the licensee when the Agency determines that:

(1) radioactive material has been properly disposed;

(2) reasonable effort has been made to eliminate residual radioactive contamination, if present; and,

(3) (a) a radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with Agency requirements; or,
(b) other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with Agency requirements.